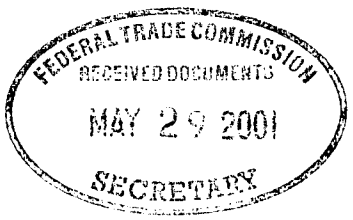
UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION



In the Matter of	)	
Schering-Plough Corporation, a corporation,	)	
Upsher-Smith Laboratories, Inc., a corporation,	)	**Docket No. 9297**
and	)	
American Home Products Corporation, a corporation.	)	

UPSHER-SMITH'S OPPOSITION TO
COMPLAINT COUNSEL'S MOTION TO AMEND THE PROTECTIVE ORDER

Two weeks ago, Complaint Counsel sought to block ***all*** in-house attorneys from having access to Confidential Discovery Material. That effort failed, as Your Honor entered a protective order allowing access to such materials by designated in-house attorneys, not to exceed two per Respondent. Now Complaint Counsel seeks to block access by the sole in-house attorney designated by Respondent Upsher-Smith. This effort, if successful, would have the same effect upon Upsher-Smith as would have Complaint Counsel's initial effort to block in-house attorneys categorically from Confidential Discovery Materials.

As established below, Complaint Counsel's renewed effort is based on fundamental misunderstandings of fact as to the responsibilities of Mark Robbins, Upsher-Smith's only in-house counsel. While Mr. Robbins may have had responsibilities involving "competitive decisionmaking" during a 1994-96 stint with Upsher-Smith, he has not had any since rejoining the company in 1998. Contrary to Complaint Counsel's assertions, Mr. Robbins' current

responsibilities are quintessentially legal in nature and are no different than those of in-house counsel at other pharmaceutical manufacturers.

Mr. Robbins's Current Responsibilities Are Legal In Nature

Mark Robbins obtained a Juris Doctor degree from St. Louis University in 1991. He is admitted to the Minnesota and Missouri Bars. He recently was elected Chairman of the Food & Drug Section of the Minnesota Bar Association. He holds an adjunct faculty appointment at William Mitchell College of Law to teach Food and Drug Law. As Mr. Robbins explained in his deposition, at Upsher-Smith he currently bears responsibility in a number of discrete areas including regulatory affairs, clinical affairs, quality assurance, and intellectual property. Robbins Tr. at 13. In all of these areas, his responsibilities are legal in nature.[1]

As to regulatory affairs, Mr. Robbins directs all of Upsher-Smith's interactions with the Food and Drug Administration ("FDA") as well as the Drug Enforcement Administration ("DEA"). This responsibility includes ensuring that Upsher-Smith complies with the rules and regulations of both of these government agencies. Mr. Robbins provides legal advice to the company on the process and procedures involved with filing New Drug Applications and Abbreviated New Drug Applications. He secures product approvals from both of these agencies and counsels the company on compliance with labeling and advertising laws. He directs the filing of annual reports on products with the FDA and DEA. He also manages and directs the activities of Upsher-Smith's outside Food and Drug Law counsel.

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[1] The factual statements in this memorandum pertaining to Mr. Robbins's responsibilities are established by the accompanying Declaration of Mark S. Robbins.

As to clinical affairs, Mr. Robbins advises on clinical trials to ensure that the procedures for these trials follow FDA rules and regulations. Mr. Robbins is responsible for negotiating contracts with outside research organizations that conduct clinical trials on behalf of Upsher-Smith. He does not have any direct role or oversight in the research and development of the actual products designed for use in these clinical trials. Rather Mr. Robbins advises Upsher-Smith on the legal aspects of safety and efficacy issues that arise during these clinical trials. Mr. Robbins also counsels Upsher-Smith on whether post-market clinical studies need to be conducted either due to mandated FDA regulation or product complaints. He is responsible for coordinating with outside counsel on product liability issues as well.

As to internal quality assurance programs, Mr. Robbins advises the company to ensure that Upsher-Smith's products are being developed and maintained safely and in accordance with all applicable federal regulations.

Finally, Mr. Robbins has responsibility for managing the legal aspects of Upsher-Smith's intellectual property. He is in charge of drafting and reviewing Upsher-Smith's confidential disclosure agreements relating to the company's intellectual property. Mr. Robbins selects and works very closely with outside patent and trademark counsel to protect and enforce Upsher-Smith's intellectual property rights.

Complaint Counsel's Concerns Are Meritless

Complaint Counsel's description of Mr. Robbins's current activities is misleading. Complaint Counsel states that Mr. Robbins has "authority over new product development" (pp. 1-2) and that his responsibilities include "management of the research and development group, the quality services laboratory, project management, clinical affairs, quality assurance and regulatory affairs" (p. 2). But, as discussed above, Mr. Robbins has such "authority" and "responsibilities"

only to the extent of assuring compliance with relevant rules and regulations of the FDA, DEA, or other legal bodies. These activities are perfectly consistent with the usual and traditional role of in-house counsel.

As Mr. Robbins explained in his deposition, he is in his second stint with Upsher-Smith. He first worked for Upsher-Smith from November 1994 until November 1996, and then returned in March 1998. In his first stint, his responsibilities included non-legal activities, and he described those activities in his deposition. But, as he also described in his deposition, he has worked in a legal capacity ever since his return in March 1998. During Mr. Robbins's eighteen-month absence from Upsher-Smith, the company hired Chuck Woodruff, Vice President of Operations, who took over many of Mr. Robbins's non-legal activities. Vickie O'Neill, Upsher-Smith's Vice President of Business Development, also assumed some of Mr. Robbins's non-legal responsibilities. Mr. Woodruff and Ms. O'Neill kept those responsibilities even after Mr. Robbins returned to the company. For this reason, in his deposition Mr. Robbins attempted to distinguish between his two stints with Upsher-Smith. Robbins Tr. at 13 (describing "current position"), 14 (noting start date of second stint), 15-16 (noting dates of first stint), 17 (describing responsibilities during first stint), 18 (testifying about after he "came back to Upsher-Smith"), 19 (testifying about "prior term at Upsher-Smith"). Notably, Complaint Counsel ignores this testimony and cites only to testimony concerning Mr. Robbins's initial stint to support their motion. Mem. at 2 (citing Robbins Tr. at 17).

Critically, Mr. Robbins no longer has any responsibility whatsoever for designing new products, developing marketing strategy, analyzing competitive conditions, establishing launch dates, setting prices, or other activities that could fairly be characterized as "competitive

decisionmaking." Thus, under the *Matsushita* and *U.S. Steel* cases cited by Complaint Counsel, Mr. Robbins is entitled to have access to Confidential Discovery Materials.

Complaint Counsel paraphrases inaccurately from the deposition of Upsher-Smith CFO Paul Kralovec. Mem. at 2. In the context of questions about the June 1997 patent settlement, Mr. Kralovec testified that Upsher did not have in-house counsel ***at that time***. Kralovec Tr. at 157. Mr. Robbins did not work for Upsher-Smith at that time. But Mr. Kralovec expressly noted that Mr. Robbins is inside counsel ***now***, although those terms are not technically part of his title. Kralovec Tr. at 157-58.

Admittedly, Mr. Robbins's title of Vice President of Scientific Affairs is not particularly descriptive of his responsibilities. But Complaint Counsel had the opportunity to explore Mr. Robbins's current responsibilities during his deposition, and chose not to do so in any depth. When Complaint Counsel first objected to Mr. Robbins having access to Confidential Discovery Materials, we responded by providing detailed information on Mr. Robbins's responsibilities. Complaint Counsel ignored this information in its motion.

Complaint Counsel notes that a third party has expressed concern over Mr. Robbins's access to "Confidential Discovery Materials" materials. Complaint Counsel neglects to note that this concern arose strictly from Mr. Robbins's title. The third party, who has contacted undersigned counsel, knew nothing of Mr. Robbins's actual responsibilities. Obviously, Mr. Robbins's entitlement to have access to sensitive materials must be determined by his actual responsibilities rather than by his title. *Matsushita*, 929 F.2d at 1579-80 (holding that "denial of access sought by in-house counsel on sole ground of status as a corporate officer is error."). We note that designated in-house counsel from Schering and AHP also hold similar titles ("Staff Vice

President" and "Executive Vice President"), but that Complaint Counsel has not seen fit to challenge their entitlement to Confidential Discovery Material.[2]

At bottom, Complaint Counsel's challenge to Mr. Robbins amounts to nothing more than the same argument it recently advanced in advocating a categorical ban on in-house counsel having access to sensitive materials. Complaint Counsel then argued that in-house counsel could not be trusted with sensitive materials because they "routinely interact with business decision makers." Complaint Counsel's May 7, 2001 Mem. Re Protective Order at 2. Your Honor necessarily rejected such an argument in granting access to a limited number of in-house counsel, and that decision need not be revisited now.

Mark Robbins serves as in-house counsel, and his having access to Confidential Discovery Materials will be critical to Upsher-Smith's defense. Among those on Upsher-Smith's legal defense team, Mr. Robbins is uniquely qualified to understand and interpret certain documents relevant to this case, including New Drug Applications, Abbreviated New Drug Applications and product launch plans. Upsher-Smith should not be denied his expertise and legal analysis on these matters, particularly when his counterparts at Schering and AHP will be assisting their respective defense teams without such constraints. Mr. Robbins will execute the declaration required of all in-house counsel, and all concerned parties can rest assured that he will honor his declaration.

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[2] Upsher-Smith would be willing to modify Mr. Robbins's title to more precisely describe his responsibilities, if Your Honor were to decide that such a change would be helpful to assuage the concerns of third parties.

CONCLUSION

Complaint Counsel's motion to amend the Protective Order should be denied. Mr. Robbins should have access to Confidential Discovery Materials.

Dated: May 29, 2001

Respectfully submitted,

WHITE & CASE LLP

By: _____

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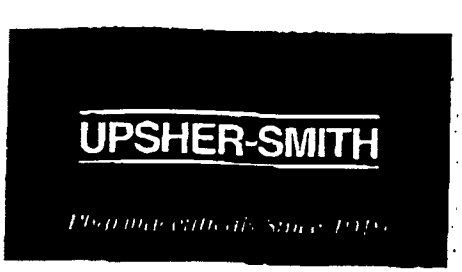

DECLARATION OF MARK S. ROBBINS

I, Mark S. Robbins, hereby declare:

1. I am currently employed with Upsher-Smith Laboratories, located at 14905 23rd Avenue, North, Minneapolis, MN 55447-4709. My current title is Vice President, Scientific Affairs.

2. I obtained a Juris Doctor degree from St. Louis University in 1991 and am admitted to the Minnesota and Missouri Bars. I was recently elected Chairman of the Food & Drug Section of the Minnesota Bar Association. I also hold an adjunct faculty appointment at William Mitchell College of Law to teach Food and Drug Law.

3. I currently bear responsibility in a number of discrete areas including regulatory affairs, clinical affairs, quality assurance, and intellectual property. In all of these areas, my responsibilities are legal in nature.

4. I direct all of Upsher-Smith's interactions with the Food and Drug Administration ("FDA") as well as the Drug Enforcement Administration ("DEA"). This responsibility includes ensuring that Upsher-Smith complies with the rules and regulations of both of these government agencies.

5. I provide legal advice to the company on the process and procedures involved with filing New Drug Applications and Abbreviated New Drug Applications. I also secure product approvals from both the FDA and DEA and counsel the company on compliance with labeling and advertising laws.

6. I direct the filing of annual reports on products with the FDA and DEA and manage and direct the activities of Upsher-Smith's outside Food and Drug law counsel.

7. I advise on clinical trials to ensure that the procedures for these trials follow FDA rules and regulations.

8. I am responsible for negotiating contracts with outside research organizations that conduct clinical trials on behalf of Upsher-Smith.

9. I do not have any direct role or oversight in the research and development for the actual products designed for use in these clinical trials.

10. I advise Upsher-Smith on the legal aspects of safety and efficacy issues that arise during these clinical trials. I also counsel Upsher-Smith on whether post-market clinical studies need to be conducted either due to mandated FDA regulation or product complaints.

11. I am responsible for coordinating with outside counsel on product liability issues as well.

12. As to internal quality assurance programs, I advise the company to ensure that Upsher-Smith's products are being developed and maintained safely and in accordance with all applicable federal regulations.

13. I manage all legal aspects of Upsher-Smith's intellectual property. I am in charge of drafting and reviewing Upsher-Smith's confidential disclosure agreements relating to the company's intellectual property.

14. I select and work very closely with outside patent and trademark counsel to protect and enforce Upsher-Smith's intellectual property rights.

15. I am in my second stint with Upsher-Smith, as I first worked for Upsher-Smith from November 1994 until November 1996, and then returned in March 1998.

16. In my first stint, my responsibilities included non-legal activities. I have, however, worked in a legal capacity ever since my return to Upsher-Smith in March 1998.

17. During my eighteen-month absence from Upsher-Smith the company hired Chuck Woodruff, Vice President of Operations, who took over many of my non-legal activities.

18. Vickie O'Neill, Upsher-Smith's Vice President of Business Development, also assumed some of my non-legal responsibilities.

19. Mr. Woodruff and Ms. O'Neill kept those responsibilities even after I returned to the company.

20. I no longer have any responsibility whatsoever for designing new products, developing marketing strategy, analyzing competitive conditions, establishing launch dates, setting prices, or other activities that could fairly be characterized as "competitive decisionmaking."

21. I will execute the declaration required of all in-house counsel, and I will honor the declaration.

I declare under penalty or perjury that the foregoing is true and correct. Executed on May 29, 2001.

Mark S. Robbins

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ORDER

Upon consideration of Complaint Counsel's Motion to Amend The Protective Order, Upsher-Smith's opposition thereto, and the record as a whole, it is hereby **ORDERED** that the Motion is **DENIED**.

Date: _____

_____
D. Michael Chappell
Administrative Law Judge

CERTIFICATE OF SERVICE

I hereby certify that on this 29th day of May 2001 I caused copies of the foregoing Upsher-Smith's Opposition To Complaint Counsel's Motion To Amend The Protective Order to be served upon the following by hand delivery:

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